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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,255	11/25/2003	Matthew Romey	032722-681	4096

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/720,255

Applicant(s)

ROMEY ET AL.

Examiner

Maureen M. Wallenhorst

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-15 is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1743

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). In addition, priority to provisional application serial no. 60/434816 has not been claimed.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprise". Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities: Applicants are requested to provide a sentence in the specification after the title of the invention claiming priority to provisional application serial no. 60/434,816.

Appropriate correction is required.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1743

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by either patent to Miyazaki et al (5,308,849 and 5,438,060).

Both patents to Miyazaki et al teach of a composition comprising benzethonium chloride, the buffering agents potassium dihydrogen phosphate and disodium hydrogen phosphate, sodium chloride and water. See example 6 in column 5 of Miyazaki et al (5,308,849) and example 4 in column 4 of Miyazaki et al (5,438,060).

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10-212220.

JP 10-212220 teaches of a composition comprising 0.001-5 wt% of benzethonium chloride and sodium bicarbonate. See the English language abstract of JP 10-212220.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by any one of JP 7-258050, Shore, Gaffar or Chiang.

Each of JP 7-258050, Shore, Gaffar and Chiang teach of compositions comprising benzethonium chloride and sodium bicarbonate. See the English language abstract of JP 7-252050, claims 1, 3, 9 and 13 of Shore, example 1 in column 6 of Gaffar and the table in column 6 of Chiang.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Espino et al.

Art Unit: 1743

Espino et al teach of a composition comprising a buffering agent such as potassium phosphate or sodium bicarbonate, a preservative such as benzethonium chloride and a tonicity agent such as sodium chloride. See column 2 in Espino et al.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Boctor et al.

Boctor et al teach of a composition comprising a sodium phosphate buffer and a benzethonium chloride bacteriostatic agent. See lines 52-55 in column 7 and lines 1-6 in column 8 of Boctor et al.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-212220.

For a teaching of JP 10-212220, see previous paragraphs in this Office action.

JP 10-212220 fails to teach of the same concentration levels for the buffering agent as recited in instant claims 4-6. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to vary the concentration of the buffering agent in the

Art Unit: 1743

composition taught by JP 10-212220 to the levels recited in instant claims 4-6 since concentration is a result effective parameter that can be varied depending upon the intended use of the composition and the optimization of a particular procedure.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over either patent to Miyazaki et al. For a teaching of both patents to Miyazaki et al, see previous paragraphs in this Office action.

Miyazaki et al fail to teach of the same concentration levels for the components of the composition as recited in instant claim 8. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to vary the concentration of the components in the composition taught by both patents to Miyazaki et al to the levels recited in instant claim 8 since concentration is a result effective parameter that can be varied depending upon the intended use of the composition and the optimization of a particular procedure.

16. Claims 9-15 are allowable over the prior art of record since none of the prior art of record teaches or fairly suggests sterilizing a pH buffer containing benzethonium chloride and one of the recited buffers with gamma radiation and calibrating pH electrodes with the pH buffer after sterilization.

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: GB 1,053,615, which teaches of a composition containing benzethonium chloride and sodium bicarbonate.

Art Unit: 1743

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 14, 2004

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1700